DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 25, 2015

HealthTronics Incorporated
Ms. Maritza Ward
Manager, Regulatory Affairs
9825 Spectrum Drive, Building 2
Austin, Texas 78717

Re: K141110
Trade/Device Name: Cryocare CS® Surgical System
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: May 20, 2015
Received: May 21, 2015

Dear Ms. Ward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141110

Device Name
Cryocare CS Surgical System

Indications for Use *(Describe)*

The Cryocare CS™ Surgical System is intended for use in open, minimally invasive or endoscopic surgical procedures in the areas in general surgery, urology, gynecology, oncology, neurology, dermatology, ENT, proctology, pulmonary surgery and thoracic surgery. The system is designed to freeze/ablate tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts.
In addition, the system is intended for use in the following indications:

General Surgery
- Destruction of warts or lesions
- Palliation of tumors of the oral cavity, rectum and skin
- Ablation of leukoplakia of the mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, perianal condylomata, pilonidal cysts, actinic and seborrheic keratoses, cavernous hemangiomas, recurrent cancerous lesions

Urology
- Ablation of prostate tissue in cases of prostate cancer and benign prostatic hyperplasia
- Gynecology
- Ablation of malignant neoplasia or benign dysplasia of the female genitalia

Oncology
- Ablation of cancerous or malignant tissue
- Ablation of benign tumors
- Palliative intervention

Neurology
- Freezing of nerve tissue in pain management/cryoanalgesia

Dermatology
- Ablation or freezing of skin cancers and other cutaneous disorders

Proctology
- Ablation of benign or malignant growths of the anus or rectum
- Ablation of hemorrhoids

Thoracic Surgery
- Ablation of arrhythmic cardiac tissue
- Ablation of cancerous lesions

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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HealthTronics™

Cryocare CS® Surgical System
510(k) Summary K141110

DATE: May 20, 2015

COMPANY:

Endocare, a wholly owned subsidiary of
HealthTronics, Inc.
9825 Spectrum Drive, Building 2
Austin, TX 78717

CONTACT:

Maritza Ward
Manager, Regulatory Affairs
Telephone: (512) 439-8361
Fax: (512) 439-8311

PROPRIETARY TRADE NAME CryoCare CS® Surgical System

CLASSIFICATION NAME: Cryosurgical Unit and Accessories

CLASS: II

PRODUCT CODE: GEH

REGULATION NUMBER: 21 CFR 878.4350

PREDICATE DEVICE:

Cryocare CS®-3 Surgical System	K101333	Cleared 06/14/2010
Endocare® 2.4mm V-Probe™ Cryoprobe	K101333	Cleared 06/14/2010
Endocare® 2.4 mm Cryoprobe	K011074	Cleared 02/28/2006

PRODUCT DESCRIPTION:

The Endocare™ Cryocare CS® Surgical System is a mobile console system intended for cryoablative tissue destruction. The system consists of a compact, easy to operate console and associated accessories that include cryoprobes to deliver cold temperatures to the targeted tissue, and TempProbe® devices to monitor temperatures in the surrounding tissue.

INDICATIONS FOR USE

The Cryocare CS Surgical System is intended for use in open, minimally invasive or endoscopic surgical procedures in the areas in general surgery, urology, gynecology, oncology, neurology, dermatology, ENT, proctology, pulmonary surgery and thoracic surgery. The system is designed to freeze/ablate tissue by the application of extreme

cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts.
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- Ablation of hemorrhoids

Thoracic Surgery
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- Ablation of cancerous lesions

TECHNOLOGICAL CHARACTERISTICS:

The proposed Cryocare CS Surgical System console and cryoprobe designs are identical to their predicates with the exception of

- minor hardware and software updates, relative to the console
- a modification to the material used to fabricate the vacuum sleeve for vacuum insulated cryoprobes

- a new right-angle handle design option for the cryoprobes offered in 1.7 mm and 2.4 mm diameters.

The subject designs have the same fundamental technological features and intended use and are compatible with the same Cryocare CS Surgical System consoles and accessories as their predicate designs.

NON-CLINICAL TESTING

Appropriate product testing was performed on all subject devices to evaluate conformance to product specifications and equivalence to the predicate designs. Verification and validation for the proposed modifications were conducted in accordance with internal protocols conforming to international standards and FDA guidance documents.

Verification /Validation Activities

- Performance Testing
  - Isotherm Testing
  - Functional Testing (ice-ball necking, shaft leak, noise)
- Shelf-Life Testing
- Electrical Safety Testing
- Electromagnetic Compatibility Testing
- Software Verification and Validation

CONCLUSION:

Based on a comparison of indications for use and technological characteristics, the proposed devices have demonstrated substantial equivalence to their predicates and are shown to be safe and effective for their intended use.